

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION

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HON. ROBERT B. KUGLER
Civil No. 19-2875 (RBK/JS)

**MOTION BY THE AUROBINDO AND TORRENT DEFENDANTS TO
QUASH PLAINTIFFS' SUBPOENAS ISSUED TO ALCAME CORPORATION, AXIS
CLINICALS, CATALENT, GIBRALTER LABORATORIES, INC., MEDICAL AFFAIRS
COMPANY, MERIDIAN CONSULTING, NOVARTIS PHARMACEUTICAL , PERITT
LABORATORIES, RISING PHARMACEUTICALS, SDS ENVIRONMENTAL
SERVICES, SIPRA LABS LIMITED, TOXROX CONSULTING, LLC**

Defendants, Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc. and Aurolife Pharma, LLC (hereinafter "Aurobindo entities") and Defendants Torrent Pharmaceuticals, Ltd. and Torrent Pharma, Inc. (hereinafter "Torrent entities," and together with the Aurobindo entities the "Moving Defendants") pursuant to Federal Rule of Civil Procedure 45(d)(3), hereby file this Motion to Quash the Plaintiffs' Subpoenas issued to Alcame Corporation, AXIS Clinicals, Catalent, Gibralter Laboratories, Inc., Medical Affairs Company, Meridian Consulting, Novartis Pharmaceutical , Peritt Laboratories, Rising Pharmaceuticals, SDS Environmental Services, Sipra Labs Limited, ToxRox Consulting, LLC, (hereinafter "Third Parties") and aver as follows:

I. FACTS AND PROCEDURAL BACKGROUND

1. The Third Parties consist of vendors, manufacturers, re-labelers, repackagers, and consultants, and are all non-parties to this litigation.

2. Some of these Third Parties were hired by the Aurobindo defendants as consultants to their legal counsel.

3. On October 15, 2020, plaintiffs' counsel served subpoenas to the Third Parties seeking information related to their: (1) Corporate Organization; (2) Contracts; (3) Communications with relevant parties; (4) ANDA and DMF file documents; (5) Nitrosamine Contamination; (6) Recall Related Documents; (7) Quarantine and/or Destruction of products; (8) Communications with the FDA; (9) Testing Data; (10) Solvent Manufacturing, Recovery, and Recycling; and (11) Toxicology Assessments. *See Subpoenas served on Third Parties, attached hereto as Exhibit "A."*

4. Additionally, throughout the eleven aforementioned requests, plaintiffs requested "communications" and "documents" pertaining to several of these requests. *See Exhibit "A."*

5. Plaintiffs' definitions of "communications" and "documents" are all encompassing, and do not contemplate "communications" and "documents" that are subject to the attorney-client privilege, the work product doctrine, and this Honorable Court's Confidentiality and Protective Order as outlined in Dkt. 139. *See Id.*

6. Furthermore, plaintiffs' subpoenas encompass requests for documents and communications beyond the scope of this Honorable Court's rulings on macro discovery issues (corrected Order entered November 26, 2019) as the subpoenas request information related to all products beyond those of Valsartan. *See Id. at p. 6, definition of "sartan," "ARB," and "recalled products," and "Active Pharmaceutical Ingredient."*

7. Definitions aside, plaintiffs' counsel did not comply with the requirements of Federal Rule of Civil Procedure 45 insofar as plaintiffs' failed to give notice to the Moving Defendants about the service of the subpoenas to any of the Third Parties.

8. Furthermore, even though not all Third Parties were in direct contact with the Moving Defendants are unaware of what information or documentation the Third Parties possess,

which may encompass information or documents protected by this Honorable Court's Confidentiality and Protective Order, the attorney-client privilege and work product doctrine.

II. STANDING

9. "Generally, any motion to quash or modify a subpoena directed towards a non-party, must be brought by the non-party itself. *Schmulovich v. 1161 Rt. 9 LLC*, No. CIV.A. 07-597FLW, 2007 WL 2362598, at *2 (D.N.J. Aug. 15, 2007) (citing *Thomas v. Marina Assocs.*, 202 F.R.D. 433, 434–435 (E.D. Pa. 2001)).

10. "However, a party to the action will have standing to quash or modify a non-party subpoena when it claims a privilege or privacy interest in the information sought from the nonparty." *Id.*

11. In this case, the Moving Defendants are claiming the subpoenas directed to the Third Parties seek information protected by the attorney-client privilege, the work product doctrine, and encompass information beyond the scope of this Honorable Court's rulings on macro discovery issues.

III. LEGAL ARGUMENT

A. Plaintiffs' Subpoenas are outside the Scope of Discovery as Provided by the Federal Rules and as Limited by this Honorable Court

12. Pursuant to Federal Rule of Civil Procedure 26(b)(1):

Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any **nonprivileged matter** that is relevant to any party's claim or defense and **proportional to the needs of the case**, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

13. In this case, this Honorable Court entered a Confidentiality and Protective Order (DKT 139) contemplating that the information sought by plaintiffs' subpoenas to the Third Parties constitute protected information. *See Confidentiality and Protective Order*, DKT. 139 at ¶ 14.

14. Additionally, this Honorable Court issued an Order on macro discovery wherein plaintiffs' requests for information pertaining to products other than Valsartan, were denied. *See Corrected Order dated November 26, 2019* at ¶ 4.

15. In direct contradiction to this Honorable Courts' Orders regarding Confidentiality and macro discovery, plaintiffs have served the subpoenas as depicted in *Exhibit "A,"* and requested certain documents and communications as follows:

16. Plaintiffs' first request, documentation pertaining to the Third Parties' Corporate Organization, are overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it is not limited to the recall of Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

17. Plaintiffs' second request, documentation pertaining to Contracts, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

18. Additionally, the second request contains terms such as "cGMP compliance," FDA Advocacy or Communication," "public relations," "crisis management" and "recall management," which are overbroad, vague and ambiguous, and encompass documents protected by attorney-client privilege, the work product doctrine, and the Confidentiality and Protective Order.

19. Plaintiffs' third request, communications with relevant parties, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks documents regarding

all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

20. Plaintiffs' fourth request, ANDA and DMF File Documents, is overbroad, unduly burdensome, and not proportionate to the needs of the Action in that it seeks documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

21. Additionally, plaintiffs' fourth request seeks "communications" that are protected by the attorney-client privilege and the work product doctrine.

22. Plaintiffs' fifth request, "communications" and "documents" related to nitrosamine contamination, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

23. Additionally, plaintiffs' fifth request seeks "communications" and "documents" that are protected by the attorney-client privilege, the work product doctrine, and this Honorable Court's confidentiality and Protective Order entered in this litigation.

24. Plaintiffs' sixth request, related to recall related documents, seeks "documents" and "communications" regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

25. Further, plaintiffs' sixth request encompasses "communications" and "documents" protected by attorney-client privilege, the work product doctrine, and the Confidentiality and Protective Order entered in this litigation.

26. Plaintiffs' seventh request, related to quarantine and/or destruction, seeks "communications" and "documents" regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

27. Additionally, plaintiffs' seventh request encompasses "communications" and "documents" protected by attorney-client privilege, the work product doctrine, and the Confidentiality and Protective Order entered in this litigation.

28. Plaintiffs' eighth request, related to communications with the FDA, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

29. Further, plaintiffs' eighth request encompasses "communications" and "documents" protected by attorney-client privilege, the work product doctrine, and the Confidentiality and Protective Order entered in this litigation.

30. Plaintiffs' ninth request, related to testing data, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

31. Moreover, plaintiffs' ninth request encompasses "communications" and "documents" protected by attorney-client privilege, the work product doctrine, and the Confidentiality and Protective Order entered in this litigation.

32. Plaintiffs' tenth request, related to solvent manufacturing, recovery, and recycling, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks

documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

33. Additionally, plaintiffs' tenth request encompasses "communications" and "documents" protected by attorney-client privilege, the work product doctrine, and the Confidentiality and Protective Order entered in this litigation.

34. Plaintiffs' eleventh request, related to toxicology assessments, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

35. Finally, plaintiffs' eleventh request encompasses "communications" and "documents" protected by attorney-client privilege, the work product doctrine, and the Confidentiality and Protective Order entered in this litigation.

B. Plaintiffs Failed to Comply with the Requirements of Federal Rule of Civil Procedure 45

36. Federal Rule of Civil Procedure 45 provides:

[i]f the subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, then before it is served on the person to whom it is directed, a notice and a copy of the subpoena must be served on each party.

FRCP 45(a)(1).

37. This notice requirement contemplates that the plaintiffs' would be required to give notice to the Moving Defendants prior to serving the subpoenas on the Third Parties. *See Coleman-Hill v. Governor Mifflin Sch. Dist.*, 271 F.R.D. 549, 552 (E.D. Pa. 2010) (citations omitted).

38. As plaintiffs' failed to provide notice to the Moving Defendants prior to serving the subpoenas, plaintiffs' have failed to comply with the requirements of Federal Rule of Civil Procedure 45.

39. Based on the forgoing, plaintiffs' have requested documents that are beyond the scope of discovery as provided in Federal Rule of Civil Procedure 26(b)(1), this Honorable Court's Confidentiality and Protective Order, and this Honorable Court's ruling on macro discovery issues, and have failed to Comply with Federal Rule of Civil Procedure 45.

40. Accordingly, plaintiffs' subpoenas issued to the Third Parties must be quashed.

41. Alternatively, a Protective Order must be entered prohibiting the disclosure of proprietary information, information related to trade secrets, and documents and communications protected by the attorney-client privilege and the work product doctrine.

Dated: October 29, 2020

Respectfully submitted,

s/ Jessica M. Heinz

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